

R E M A R K S

The Examiner provides a number of rejections and we list them here in the order in which they are addressed:

- I. Claims 1, 4-9 and 12-16 are rejected under 35 U.S.C. §112 ¶1 as allegedly failing to comply with the enablement requirement.
- II. Claims 9 and 12-16 are rejected under the judicially created doctrine of obviousness type double patenting over:
 - A. Claims 1-9 of US Patent No. 5,874,087
 - B. Claims 22-28 of US Patent No. 5,958,422

I. The Claims Are Enabled

The Examiner has rejected all of the claims as not enabled pursuant to 35 U.S.C. §112 ¶1. Applicants disagree and herein incorporate by reference all arguments presented previously to this same rejection. The Applicant's argue below in rebuttal of the Examiner's erroneous analysis presented in the pending Final Office Action.

The Examiner has reasserted the present enablement rejection on the basis that the Applicants' claimed embodiment encompasses "... insertion ... anywhere in the nucleic acid sequence ..." and "any plant virus or any plant RNA virus". *Office Action* pg. 3. As argued in the previous response, the Applicants believe that sufficient guidance and experimental detail is present in the specification to enable one having ordinary skill in the art to make and use the invention.¹ Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 1 and 9 to recite that the oligonucleotide is inserted at a location that codes for "an exposed part" of the virus coat protein. *See Applicants' Specification*, pg. 12 *ln* 19-25. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

¹ It is well settled that to satisfy the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art. *In re Marzocchi*, 439 F.2d 223 (CCPA 1971).

Further, the Applicants challenge the Examiner to explain why, since *Comoviruses* are admittedly enabled, Claims 8 and 16 are rejected? At worst, Claims 8 and 16 should be identified as “objected to” as being dependent on a rejected base claim.

II. The Examiner Has Misinterpreted Uhde et al.

The Examiner has reasserted the belief that:

... the claims are still broad in that insertion is in *any site* of the gene encoding the plant viral coat protein in *any plant virus*.

Office Action pg. 2 ¶ 1. In the last Office Action response, the Applicants submitted the Uhde et al. publication as evidence that oligonucleotide addition may occur at any site and in any plant virus. The Examiner has not yet realized that Uhde et al. teaches exactly these points. Instead, the Examiner believes that Uhde et al.:

... is not on point, because it ... teaches expression of a target insert as an amino-terminal extension ...

Office Action pg. 5, ln 7-8. This is precisely the type of evidence that rebuts the Examiner’s argument by showing that *any site* (i.e., not just insertions) may be used for an expression transcript. Further, Uhde et al. uses a *different virus* than the Applicants’, thereby rebutting the second half of the Examiner’s argument.

In reference to the above claim amendments, the Applicants point out that Uhde et al. also teaches that the amino-terminal coat proteins are “displayed on the surface” of the virus.

The Applicants respectfully request that the Examiner reconsider Uhde et al., in its entirety, because the reference is clearly “on point”.

III. The Examiner Has Misinterpreted Porta et al.

The Examiner also attempts to substantiate the present rejection upon Porta et al., that allegedly shows that the insertion of an Arg-Gly-Asp motif results in a non-infective virus.

Office Action pg. 4. First, the Applicant’s fail to see the relevance of this observation in relation to the presently claimed embodiments.² Second, Porta et al. does not teach that the Arg-Gly-Asp motif (present in the pMT7-FMDV-V virus) results in non-assembled viral particles³.

² “Infectivity” is not a claimed element.

³ The pMT7-FMDV-I virus is suggested to have “deficient assembly” when compared to wild-type CPMV but not

Further, neither Applicants' Claim 1 nor Claim 9 recites "an infective particle", only that particle assembly occurs. More to the point, the Examiner's reliance on Porta et al. is misplaced to support the general conclusions that:

... insertion of foreign nucleic acids into nonoptimal positions can lead to **noninfective** virus ...

and,

... an insert encodes an Arg-Gly-Asp motif, expression of the resulting modified coat protein resulted in particle immobilization, hence **no infection**.

Office Action pg. 4 [emphasis added]. The Examiner has misquoted Porta et al. by improperly making a general conclusion when using the terms "noninfection or no infection" because Porta et al. only teaches that, in some circumstances, systemic infection may not occur (i.e., as compared to a local infection).

In fact, Porta et al. teach that the pMT7-FMDV-V virus is fully infective:

The situation in regard to pMT7-FMDV-V is puzzling. The fact that it gives **wild-type lesions** on inoculated leaves but fails to spread systemically suggests that chimeric virus particles are fully competent for cell-to-cell movement but deficient for long-distance transport.

Porta et al., pg 954 col 2 [emphasis added]. The Applicants request the Examiner reconsider the above analysis in view of this evidence.

Aside from the above evidence showing that the Examiner has drawn incorrect conclusions from the Porta et al. reference, the Applicants remind the Examiner that a valid patent claim may, in fact, encompass inoperable embodiments.⁴ Further, it is well settled patent law that a claim may contain many inoperable elements (even though the Applicant believes this not to be the case):

... the mere possibility of inclusion of inoperative . . . [subject matter] does not prevent allowance of broad claims ... many patented claims read on vast numbers of inoperative embodiments.

Application of Cook, 439 F.2d 730, 734, n4, 735169 U.S.P.Q. 298 (CCPA 1971), and

Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid. 'It is not a function of the claims to specifically exclude . . . possible inoperative substances. . . .'

Atlas Powder Co. v. E.I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409 (Fed. Cir. 1984). Consequently, even if the Examiner is correct (which the Examiner is not) that some viruses may be completely non-infective (which the Examiner has not shown), this is not an

sufficient to prevent infectivity. *Porta et al.*, pg 954 col. 1.

⁴ The Applicants, however, have shown that all embodiments contemplated within the present specification are

appropriate basis on which to reject the presently claimed embodiments. The Applicants respectfully request the Examiner to withdraw the present rejection.

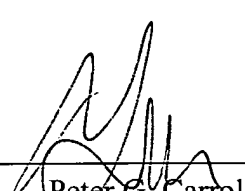
II. Double Patenting

The Examiner has rejected Claims 9 and 12-16 under the judicially created doctrine of double patenting over claims 1-9 of U.S. Patent 5,874,087 stating that the claims are not patentably distinct over the claims of the '087. The Examiner has also rejected Claims 9 and 12-16 under the judicially created doctrine of double patenting over claims 22-28 of U.S. Patent 5,958,422. Provided Applicants' claims are otherwise found allowable, Applicants may split out these claims into a separate application with the required Terminal Disclaimer. This would permit Claims 1 and 4-8 to issue. The Examiner is requested to call the undersigned prior to another Office Action in order to discuss this procedure.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617-984-0616.

Dated: March 15, 2006



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operable.